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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/563,547 | 06/12/2006 | Andrew James Evans | GHACK10.001APC | 1508 |
| 20995 | 7590 | 06/26/2008 | EXAMINER | |
| KNOBBE MARTENS OLSON & BEAR LLP | | | LEWIS, KIM M | |
| 2040 MAIN STREET | | | ART UNIT | PAPER NUMBER |
| FOURTEENTH FLOOR | | | 3772 | |
| IRVINE, CA 92614 | | | | |
| | | NOTIFICATION DATE | | DELIVERY MODE |
| | | 06/26/2008 | | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/563,547 | EVANS, ANDREW JAMES | |
| | Examiner | Art Unit | |
| | Kim M. Lewis | 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 May 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 and 9-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7 and 9-14 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: Detailed Action.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/08 has been entered.
2. As requested in the submission, claims 1, 5, 6 and 9-13 have been amended. Claims 1-7 and 9-14 are pending in the instant application.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO00/64394 ("Heaton et al.").

As regards claim 1, Heaton et al. disclose a limb protection device comprising a sleeve (12) for use in enclosing a limb. As can be seen from Fig. 5, the sleeve is sealed at one end via zip lock seal (4). Heaton et al. also disclose an integral and flexible cuff having a tapered profiled arranged to allow an appropriately sized opening

to be cut into the device (page 4, line 15-16). The end of cuff (8) may be sealed to with acrylic adhesive (9) provided on the cuff or with a separate piece of adhesive tape (page 4, lines 8-14). Applicant should note that the appropriately sized opening in the cuff is selectable to stretch around and compress against that part of the user's limb extending therethrough, to prevent the ingress of matter into the device immediately at the device opening.

Re. claim 5, as can be seen in Fig. 3, the cuff has a width greater than the wall thickness of the sleeve.

Re. claim 6, the cuff is formed from the same material as the sleeve.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 2-4, 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaton et al. in view of U.S. Patent No. 6,276,364 ("Warner").
8. As regards claim 2-4, Heaton et al. fail to teach a series of spaced apart, semi-circular protrusions integrally molded to the cuff.

However, Warner discloses a protective cuff comprising a series of spaced apart, semi-circular protrusions (banding) (see Fig. 6) integrally molded to the cuff. These bandings allow the sleeve to be fitted to the individual user (col. 5, lines 8-21).

In view of Warner, it would have been obvious to one having ordinary skill in the art to provide the device of Heaton et al. with protrusions in the form of bandings in order to allow the device to be fitted to the individual user.

Re. claim 7, Heaton et al. fail to teach the protector is formed from latex or elastic impregnated plastic. Warner, however, discloses a protective sleeve constructed from latex, which is both air and liquid impermeable, and allows for stretching of the device to fit the user's limb and form tight seal thereto.

It would have been further obvious to one having ordinary skill in the art to modify the device of Heaton et al. by substituting the material of construction (polyurethane or polyolefin) for latex for its known properties. Applicant should note that it has been held that the selection of a known material based upon its suitability for its intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Re. claims 9 and 10, note zip lock seal (4) disclosed in Heaton et al.

Re. claim 11, the cover of Heaton et al. is for use on the hand.

Re. claim 12, Heaton et al. fails to teach cover (12) is transparent. However, it would have been obvious to one having ordinary skill in the art to construct the cover from transparent material in order to view the contents and to make sure that the treatment device is functionally properly. Applicant should also note that since transparency is a desired feature, the selection of a transparent material would have been a design consideration within the skill of the art (note the above cite to *In re Leshin*).

Re. claim 13, the sleeve is constructed from a polymer integrally molded with the cuff.

Re. claim 14, note therapeutic agent discussed at page 3, lines 12-22 in Heaton et al.

Response to Arguments

Applicant's arguments with respect to claims 1-7 and 9-14 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/
Primary Examiner
Art Unit 3772

Kml
June 11, 2008